

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Brian J. Brown, Michael Davis, David Friesen, Timothy J. Ley and Sean Skubitz
Application No.:	10/800572
Filed:	March 15, 2004
For:	Improved Longitudinally Flexible Expandable Stent
Examiner:	Vy Q. Bui
Group Art Unit:	3773

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P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: S63.2N-6769-US05

APPEAL BRIEF

This is an Appeal Brief for the above-identified Application in which claims 38-40, and 44-52 were rejected in the Final Office Action mailed September 27, 2010. A Notice of Appeal was filed in this case on January 25, 2011. This brief is submitted in accordance with 37 CFR. § 41.37. The fees required under 37 CFR § 41.20(b)(2), and any petition for an extension of time required for filing this brief, are addressed in the accompanying Transmittal Letter.

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(i) Real Party in Interest

The Application is assigned to Boston Scientific Scimed, Inc. (formerly Scimed Life Systems, Inc.), One Scimed Place, Maple Grove, Minnesota 55311-1566, a Minnesota corporation and a subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 38-41 and 43-52 are pending in the application. Claims 41 and 43 have been withdrawn from consideration. Claims 1-37 and 42 were previously canceled.

Claims 38, 39, 44, 46, 47 and 49-52 have been finally rejected and are the subject of this appeal. Appellants believe that claims 40 and 48 are also rejected, as discussed below under Issue 3; however, the Final Office Action is unclear. Claim 45 was also rejected in the Final Office Action under 35 USC § 102 and 35 USC § 112, second paragraph, but the current status of claim 45 is unclear.

Subsequent to the Amendment After Final¹ filed November 24, 2010, the Examiner issued an Advisory Action on December 9, 2010, which indicated that claim 45 was allowed. The Examiner then issued a second Advisory Action, dated January 19, 2011, which indicated that the rejection of claim 45 had been overcome (see check box 5), but also indicated that claim 45 was rejected (see check box 7).

Appellants request clarification from the Examiner as to the status of the claims.

¹ The Amendment After Final filed November 24, 2010, which the Examiner refused to enter (see second Advisory Action, mailed January 19, 2011), made a non-substantive amendment to claim 45 to correct an antecedent issue.

(iv) Status of Amendments

Two Amendments have been submitted subsequent to the Final Office Action – an Amendment After Final was filed on November 24, 2010, and an Amendment on Appeal was filed on April 14, 2011.

The Amendment After Final attempted to make non-substantive amendment to claim 45 to correct an antecedent issue. The Advisory Action mailed January 19, 2011 asserts that the amendment would require further consideration (i.e. that an RCE would be necessary to enter the amendment) and refused to enter the Amendment After Final.

An Amendment on Appeal has been submitted prior to submission of this Appeal Brief. The Amendment on Appeal attempts to make the same non-substantive amendment to claim 45 that would have been made by the Amendment After Final. The Amendment on Appeal argues that the non-substantive amendment would not change the scope of the claim, and that entry of the Amendment on Appeal would moot the rejection under 35 USC § 112 and present claim 45 in better form for consideration on appeal.

At this time, the Examiner controls whether or not the Amendment on Appeal will be entered.

(v) **Summary of Claimed Subject Matter**

A summary of the representative independent claim, as required by 37 C.F.R. § 41.37(c)(1)(v), and a non-limiting listing of locations where support may be found [bracket citations] is provided as follows:

Claim 38 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body has a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of adjacent closed circumferential support structures being spaced-apart along the longitudinal axis. [FIGs. 5a (below) and 5b]. Each support structure including longitudinal struts being interconnected at apex portions. [FIGs. 5a and 5b]. The longitudinal struts and apex portions define an undulating pattern. [FIGs. 5a and 5b]. At least some of the apex portions of adjacent closed circumferential support structures are configured to longitudinally overlap one another when in the un-deployed configuration. [FIGs. 5a and 5b]. A plurality of connecting struts interconnect at least some of the adjacent closed circumferential support structures. [FIGs. 5a and 5b]. The connecting struts extend between the apex portions that overlap one another. [FIGs. 5a and 5b].

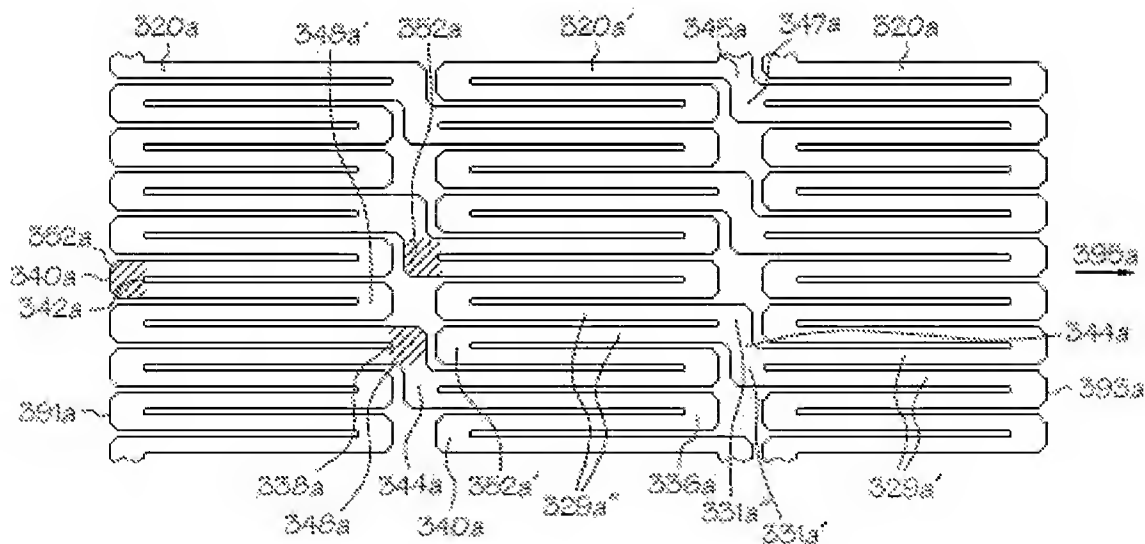


FIG. 5a

Claim 40 depends from claim 39 and requires at least some of the circumferential connecting struts to have a width greater than a width of the longitudinal struts. [FIGs. 5a and

5b].

Claim 45 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body defines a plurality of cells. [FIGs 5a and 5b]. The stent body has a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of adjacent closed circumferential support structures spaced-apart along the longitudinal axis. [FIGs. 5a and 5b]. Each support structure includes longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern. [FIGs. 5a and 5b]. A plurality of connecting struts interconnects at least some of the adjacent closed circumferential support structures. [FIGs. 5a and 5b]. The connecting struts extend between the apex portions of adjacent circumferential support structures. [FIGs. 5a and 5b]. At least some of the connecting struts have a width greater than a width of the longitudinal struts. [FIGs. 5a and 5b]. Each cell of the stent is partially defined by a connecting strut. [FIGs. 5a and 5b].

Claim 46 is directed to a stent comprising a stent body expandable between an un-deployed orientation and a deployed orientation. [FIG. 3; page 1, lines 17 – 18]. The stent body has a circumference and a longitudinal axis extending between first and second open ends. [FIG. 3; page 4, lines 19 – 20]. The stent body has a plurality of circumferential support structures, which extend generally about the circumference of the stent, the circumferential support structures being spaced-apart along the longitudinal axis. [FIGs. 5a and 5b]. Each of the circumferential support structures includes longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern. [FIGs. 5a and 5b]. At least some of the apex portions of adjacent circumferential support structures being configured to longitudinally extend past each other when in the un-deployed configuration thus providing longitudinal overlap. [FIGs. 5a and 5b]. A plurality of circumferential connecting struts interconnect at least some of the adjacent circumferential support structures, the circumferential connecting struts extending between and connected to the apex portions that extend past each other. [FIGs. 5a and 5b].

Claim 48 depends from claim 46 and requires at least some of the circumferential connecting struts to have a width greater than a width of the longitudinal struts. [FIGs. 5a and 5b].

(vi) Grounds of Rejection to be Reviewed on Appeal

Issue 1: Whether the Examiner erred in rejecting claim 45 under 35 USC § 102 or 35 USC § 112.

Issue 2: Whether the Examiner erred in rejecting claims 38, 39, 44, 46, 47 and 49-52 under 35 USC § 103 over Mathis (US 6129755) in view of Wijay (US 5824059).

Issue 3: Whether the Examiner erred in rejecting claims 38, 39, 44, 46, 47 and 49-52 under 35 USC § 103 over Mathis (US 6129755) in view of Wijay (US 5824059) and further in view of Richter (US 7534257).²

² Appellants believe the rejection under Issue 3 was intended for claims 40 and 48, which were not rejected under Issue 2.

(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claim 45 under 35 USC § 102 or 35 USC § 112, second paragraph.

The Final Office Action rejected claim 45 under 35 USC § 102 over Moriuchi (US 5879381) and under 35 USC § 112, second paragraph, citing an antecedent issue. See Final Office Action at pages 2-3.

In the Amendment After Final filed November 24, 2010, Appellants argued that claim 45 was not anticipated by Moriuchi and attempted to make a non-substantive amendment to claim 45 to correct the antecedent issue. An Advisory Action mailed December 9, 2010 indicated that claim 45 was allowed; however, a second Advisory Action mailed January 19, 2011 indicated that Appellants' reply had overcome the rejection of claim 45 (see checkbox 5) but also indicated that claim 5 was rejected (see checkbox 7).

The second Advisory Action indicated that the Amendment After Final would not be entered because the amendment to claim 45 would require further consideration. This reasoning appears to be pretextual because the amendment was non-substantive, and because the second Advisory Action also appears to indicate that claim 45 could be rejected over the references applied against the other claims. If claim 45 would be subject to a rejection over the cited references, then no additional search/consideration is necessary to form the rejection.

The current status of claim 45 is unclear.

With respect to the rejection under 35 USC § 112, second paragraph, Appellants would like to amend claim 45 to correct the antecedent issue. An Amendment on Appeal has been submitted prior to this Appel Brief, which makes a non-substantive, clarifying amendment to claim 45. The amendment is not intended to change the scope of the claim. The amendment will moot the rejection under 35 USC § 112 and will simplify issues on appeal. Appellants have requested entry of the Amendment on Appeal.

If the Amendment on Appeal is not entered, Appellants will amend claim 45 to correct the antecedent issue subsequent to the appeal.

With respect to the rejection under 35 USC § 102, is any, Appellants assert the arguments presented in the Amendment After Final filed November 24, and request that the Board reverse the rejection of claim 45 under 35 USC § 102 over Moriuchi.

Issue 2: Whether the Examiner erred in rejecting claims 38, 39, 44, 46, 47 and 49-52 under 35 USC § 103 over Mathis (US 6129755) in view of Wijay (US 5824059).

The Examiner erred in rejecting claims over Mathis in view of Wijay because the references do not disclose or suggest each limitation of any of the rejected claims. Further, the Examiner has not given a clear explanation of why a person of ordinary skill in the art would have been prompted to modify the Mathis stent as proposed in the rejection.

Overlapping Apex Portions

Independent claim 38 recites, “at least some of the apex portions of adjacent closed circumferential support structures being configured to longitudinally overlap one another.”

Independent claim 46 recites, “at least some of the apex portions of adjacent circumferential support structures being configured to longitudinally extend past each other when in the un-deployed configuration thus providing longitudinal overlap.”

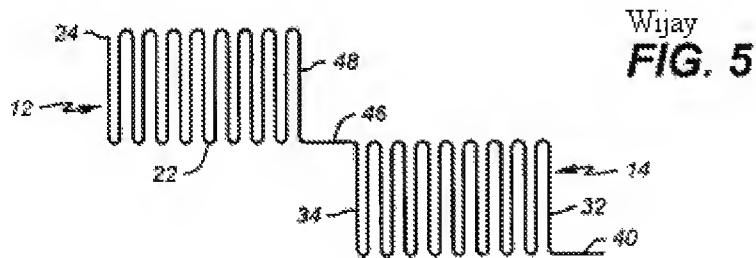
An obviousness rejection requires a suggestion of all limitations in a claim. See *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003).

The Examiner admits that Mathis does not disclose or suggest the overlapping apex portions, but asserts that Wijay does. See Final Office Action at page 4.

Wijay does not disclose or suggest the claimed overlapping apex portions. Nor does Wijay disclose “closed circumferential support structures” that have the overlapping apex portions, as required by claim 38.

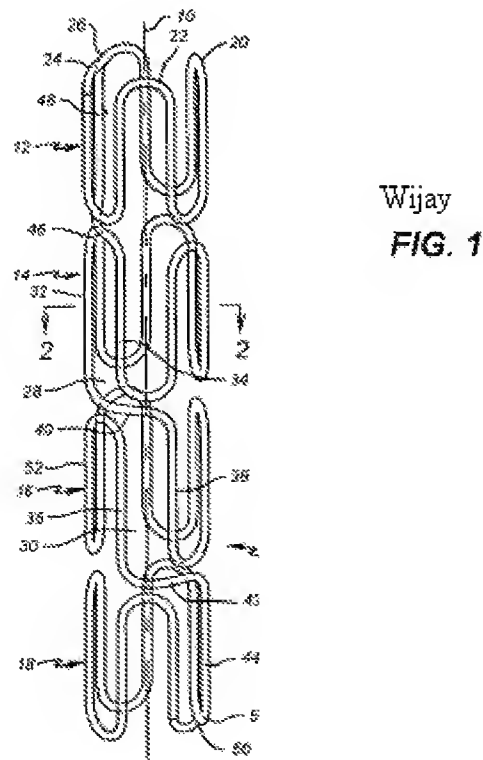
Wijay discloses two main embodiments for a stent – a first embodiment that is formed by winding a wire, as shown in Figure 1 (see e.g. column 4, lines 35-46); and a second embodiment that is formed by etching a tube, as illustrated in Figures 3 and 4 (see column 6, lines 33-36).

The Examiner asserts that the embodiment of Wijay Figures 1 and 5 teaches the overlapping apex portions. The rejection makes specific reference to Figure 5, shown below. See Final Office Action at page 4.



Thus, the Examiner appears to assert that the 90 degree turns at either end of the crosstie 46 in Figure 5 are each an “apex portion” as recited in the rejected claims, and that the 90 degree turns overlap/extend past one another as required by claims 38 and 46. The Examiner’s characterization of Wijay is traversed.

Figure 5 of Wijay does not depict an embodiment of an actual stent, but a wire in the process of being made into a stent. Wijay teaches that the configuration of Figure 5 would be wrapped on a mandrel and formed into the stent as shown in Figure 1. See e.g. column 5, lines 63-65.



In Figure 1, it is clear that the Wijay rings 12, 14, 16 are spaced along the length of

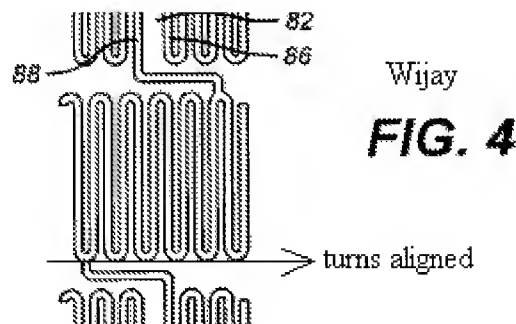
the stent, and do not include apex portions that overlap.

In response to the Examiner's assertion that the 90 degree turns have overlap, Appellants assert that the 90 degree turns disclosed by Wijay are not "apex portions" as recited in the rejected claims.

Claim 38 requires "closed circumferential support structures." The 90 degree turns are not part of a "closed circumferential support structure." The stent of Figure 1 includes open ring structures, and the 90 degree turns form a connection between two adjacent open rings. Claim 38 further recites, "each support structure including longitudinal struts interconnected at apex portions." The 90 degree turns do not connect between longitudinal struts of a given closed circumferential support structure. Therefore, the 90 degree turns of Wijay are not "apex portions" as recited in claim 38.

Claim 46 recites, "each of the circumferential support structures including longitudinal struts interconnected at apex portions." Thus, the "apex portions" of claim 46 connect between longitudinal struts of a given circumferential support structure. The 90 degree turns of Wijay do not connect between two longitudinal struts of a given ring. Thus, the Wijay 90 degree turns are not "apex portions" as recited in claim 46.

With respect to the embodiment formed by etching a tube, Wijay does not teach the required overlap. Figure 4 does show some closed rings; however, the apex portions of a given closed ring are generally aligned such that apex portions of adjacent rings do not overlap. See e.g. excerpt from Figure 4, provided below.



The text of Wijay does not mention any overlap. The Examiner has not cited to any discussion in Wijay that would establish the existence of, or any desire for, the overlap required by the rejected claims. A crosstie 46 extending between two adjacent rings 12, 14 does

not amount to the claimed overlap of apex portions.

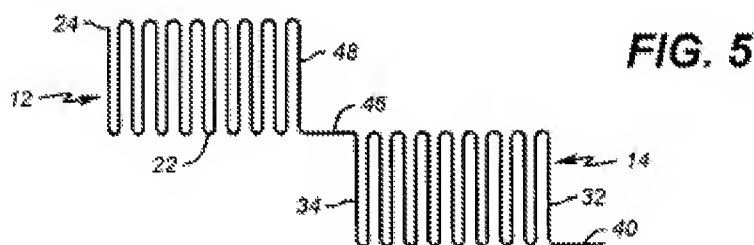
Therefore, the combination of Mathis and Wijay does not disclose or suggest each limitation of claims 38 or 46, or any claim dependent therefrom. Appellants request that the Board reverse the rejection of independent claim 38, and claims 39 and 44 dependent therefrom, and the rejection of independent claim 46, and 47 and 49-52 dependent therefrom, under 35 USC § 103 over Mathis in view of Wijay.

Reason to Modify

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

The Examiner proposes to modify the Mathis stent by providing some longer struts to cause overlapping apex portions. See Office Action at page 4. This proposal is traversed because the applied references do not disclose longer struts – the concept has been gleaned from Appellants' disclosure using impermissible hindsight.

As discussed above, Wijay does not actually teach overlap of apex portions of adjacent support structures. The Examiner has merely alleged that the concept is disclosed in Figure 5, provided below.



The Examiner has not cited to any teaching in Wijay that establishes disclosure of the concept of overlap. The Examiner has not cited to any teaching that establishes the concept of longer struts and shorter struts within a given circumferential support structure.

Nor has the Examiner cited to any prior art teaching that would have motivated a person of ordinary skill in the art to modify Mathis in a way that would achieve the claimed overlap. The applied references do not disclose the concept or provide any reason to achieve the

concept.

The Examiner asserts that Wijay teaches a concept of overlapping apex portions and a concept of circumferential connecting struts being perpendicular to longitudinal struts “apparently in order to obtain the advantage of enabling the stent portions 62, 64, 66, etc. (F 4) to be closer to each other.” The so-called “advantage” discussed by the Examiner is merely speculative – the Examiner has not cited to any teaching of such an “advantage.”

The alleged “advantage,” even if true, would only apply to the teaching of circumferential connecting struts being perpendicular to longitudinal struts, because it is unclear how the concept of ‘extended struts/overlap of apex portions of adjacent rings’ would cause the adjacent rings to be grouped closer to one another. Thus, the Examiner has not discussed any advantage associated with Wijay’s alleged disclosure of overlapping apex portions.

The Examiner proposes to “provide some longer struts” for the Mathis stent “so that it too would have this advantage.” See Final Office Action at page 4. Thus, the reasoning provided by the Examiner for modifying Mathis is to provide longer struts for the same reason that Wijay provides longer struts. However, Wijay does not teach longer struts or discuss any reason to use longer struts. As discussed above, any “advantage” that the Examiner refers to amounts to speculation.

The Examiner has not articulated a reason why a person of ordinary skill in the art would have actually modified the Mathis stent. The Examiner does not give any reason for performing the proposed modification. Therefore, the Examiner has not presented a *prima facie* case of obviousness against any claim rejected under 35 USC § 103.

Appellants request withdrawal of all rejections asserted under 35 USC § 103 applying Mathis in view of Wijay.

Issue 3: Whether the Examiner erred in rejecting claims 38, 39, 44, 46, 47 and 49-52 under 35 USC § 103 over Mathis (US 6129755) in view of Wijay (US 5824059) and further in view of Richter (US 7534257).

Although the rejection lists the same claims that are rejected over Mathis in view of Wijay, discussed under Issue 2, the rejection discusses the limitations of claims 40 and 48, which were not included in the rejection over Mathis in view of Wijay. Thus, Appellants assume

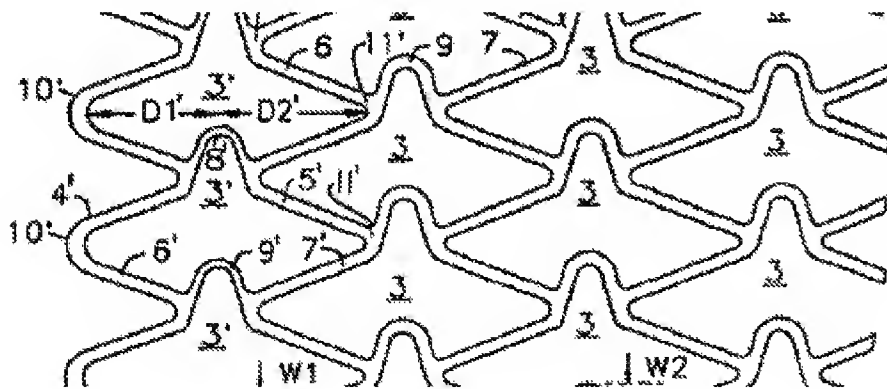
the rejection is intended for claims 40 and 48.

The Examiner erred in rejecting claims over Mathis, Wijay and further in view of Richter because the applied references do not disclose or suggest each limitation of the rejected claims.

The rejections applying Richter rely on the reasoning of the rejection applying only Mathis in view of Wijay, discussed above under Issue 2. Appellants have traversed the rejections under Issue 2, and requests that the Board reverse the rejections discussed under Issue 3 for the same reasons discussed under Issue 2.

Claims 40 and 48 each recite “at least some of the connecting struts have a width greater than a width of the longitudinal struts.”

The Examiner admits that Mathis and Wijay do not teach a connecting strut that is wider than a longitudinal strut, then cites to Richter, asserting that Richter teaches wider and thinner connecting struts. See Final Office Action at page 4.



Richter
FIG. 2

Richter Figure 2, provided above, does show connectors of different width – see e.g. connector 9 and connector 9'. However, these teachings do not meet the limitations of claims 40 or 48.

The Examiner has not cited to disclosure in Richter of a connecting strut that is wider than a longitudinal strut. Further, the Examiner has not articulated a reason why a person of ordinary skill in the art would have been prompted to modify the stent of Mathis/Wijay in a way that would result in a stent that meets the limitations of claims 40 or 48.

Therefore, a *prima facie* case of obviousness has not been presented under Issue 3.

The rejection also cites to *In re Rose*, arguing that a change in size is within the

level of ordinary skill in the art. See Final Office Action at page 5. The rejection does not propose to change the overall size (e.g. scale up) of the device, but instead proposes to change only certain portions while not changing other portions. *In re Rose* does not support the assertion made in the rejection, and the proposal to change only the portions necessary to meet the pending claims stems from impermissible hindsight.

Appellants request that the Board reverse the rejections asserted by the Examiner over Mathis in view of Wijay and further in view of Richter.

Argument Conclusion

Based on at least the foregoing arguments, Appellants respectfully assert that the rejections presented by the Examiner fail to establish a *prima facie* case of obviousness against any of the pending claims. Accordingly, Appellants respectfully request that the Board reverse all of the rejections asserted by the Examiner.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

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(viii) Claims Appendix

38. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body having a longitudinal axis extending between first and second open ends; the stent body having a plurality of adjacent closed circumferential support structures, the closed circumferential support structures being spaced-apart along the longitudinal axis; each support structure including longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern, at least some of the apex portions of adjacent closed circumferential support structures being configured to longitudinally overlap one another when in the un-deployed configuration; a plurality of connecting struts interconnecting at least some of the adjacent closed circumferential support structures, the connecting struts extending between and connected to the apex portions that overlap one another.

39. The stent of claim 38 wherein in the deployed orientation, adjacent closed circumferential support structures are offset such that the apex portions on one side of a support structure are positioned intermediate the apex portions on a facing side of an adjacent support structure.

40. The stent of claim 38 wherein at least some of the connecting struts have a width greater than a width of the longitudinal struts.

44. The stent of claim 38 wherein the undulating pattern defines a wavelength, and wherein the connecting struts are at least one half the length of the wavelength.

45. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body defining a plurality of cells, the stent body having a longitudinal axis extending between first and second open ends; the stent body having a plurality of adjacent closed circumferential support structures, the closed circumferential support structures being spaced-apart along the longitudinal axis; each support structure including longitudinal struts

interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern; and a plurality of connecting struts interconnecting at least some of the adjacent closed circumferential support structures, the connecting struts extending between the apex portions of adjacent circumferential support structures, at least some of the circumferential³ connecting struts having a width greater than a width of the longitudinal struts, each cell of the stent partially defined by a connecting strut.

46. A stent comprising: a stent body expandable between an un-deployed orientation and a deployed orientation, the stent body having a circumference and a longitudinal axis extending between first and second open ends; the stent body having a plurality of circumferential support structures, which extend generally about the circumference of the stent, the circumferential support structures being spaced-apart along the longitudinal axis; each of the circumferential support structures including longitudinal struts interconnected at apex portions, the longitudinal struts and apex portions defining an undulating pattern, at least some of the apex portions of adjacent circumferential support structures being configured to longitudinally extend past each other when in the un-deployed configuration thus providing longitudinal overlap; a plurality of circumferential connecting struts interconnecting at least some of the adjacent circumferential support structures, the circumferential connecting struts extending between and connected to the apex portions that extend past each other.

47. The stent of claim 46, wherein the adjacent circumferential support structures include a first circumferential support structure and a second circumferential support structure that is adjacent to the first circumferential support structure, and wherein in the deployed orientation, the adjacent circumferential support structures are offset such that the apex portions on one side of

³ Appellants have attempted to delete the word 'circumferential' from claim 45 by filing the Amendment on Appeal

the first circumferential support structure are positioned intermediate the apex portions on a facing side of the second circumferential support structure.

48. The stent of claim 46, wherein at least some of the circumferential connecting struts have a width greater than a width of the longitudinal struts.

49. The stent of claim 46, wherein the adjacent circumferential support structures include a first circumferential support structure, a second circumferential support structure and a third circumferential support structure, wherein the second circumferential support structure is adjacent the first and the third circumferential support structures, and wherein the circumferential connecting struts joining the first and the second support structures extend in a first direction and the circumferential connecting struts joining the second and the third support structures extend in a second direction opposite the first direction.

50. The stent of claim 46, wherein some of the longitudinal struts are longer than other longitudinal struts, and wherein the longer longitudinal struts provide the longitudinal overlap at the apex portions.

51. The stent of claim 46, wherein the circumferential connecting struts extending between the apex portions that extend past each other are angled with respect to the circumference of the stent body.

52. The stent of claim 46, wherein the undulating pattern defines a wavelength, and wherein the circumferential connecting members are at least one half the length of the wavelength.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None